K120057

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MAY 11 2012

- **510(K) SUMMARY (PER 21 CFR 807.92) -**

Date Prepared: December 23, 2011

SUBMITTER INFORMATION

510(k) Owner and Device Manufacturer:	Bioptigen, Inc.
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Contact:	Dawn Reilly-O'Dell, RAC Full Circle Regulatory Consulting, LLC +1 919 410 7497 (Phone) dreilly@bioptigen.com (Email)

DEVICE IDENTIFICATION

Trade or proprietary name:	Envisu™ Spectral Domain Ophthalmic Imaging System (SDOIS)
Common or usual name:	Spectral Domain Optical Coherence Tomography (SD-OCT)
Classification name:	Ophthalmoscope, AC-powered; Tomography, Optical Coherence
Product Codes:	HLI, OBO
Regulation Number:	886.1570

INTENDED USE

Bioptigen Envisu™ Spectral Domain Ophthalmic Imaging System (SDOIS) is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT).

The Envisu SDOIS is indicated for use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in upright or supine imaging, handheld or mounted, and is suited for imaging patients under anesthesia.

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SUBSTANTIAL EQUIVALENCE

The Envisu™ SDOIS is substantially equivalent to the predicate SDOIS in technology, safety and effectiveness. The Envisu™ SDOIS incorporates a number of design changes, but it shares the same fundamental spectral domain optical coherence tomography imaging technology and incoherent superluminiscent light emitting diode technology as the predicate SDOIS. The differences between the 2006 predicate, K063343, and the current subject SDOIS are the following design modifications incorporated to enhance device usability and performance:

- Upgraded spectrometer line-scan camera allowing 32,000 A-scans/second for faster imaging speeds with no increase in patient irradiance
- Added VHR light source option for improved axial resolution without increase in patient irradiant exposure
- Revised scan head with enhanced ergonomics including handheld operation for improved clinical flexibility and patient comfort
- Mobile transport cart with Uninterruptable Power Supply (UPS)
- Increased computer memory and processing speed
- Additional objective lens options for cornea and related anterior imaging
- Updated Information for Use labeling to parallel the system changes and a new training manual to address use of the handheld scanner
- Added spectrometer design option for increased imaging depth to 3.4 mm in air (2.5 mm in tissue) for greater depth of imaging field
- Upgraded IVVC software post-processing and visualization functionality including four new features, which are the option to register and average multiple frames, the manual Onscreen Calipers, the 3D view and the option to generate Word-based reports

Predicate Device	510(k) Holder	510(k)	Clearance Date
Spectral Domain Ophthalmic Imaging System (SDOIS)	Bioptigen, Inc.	K063343	December 13, 2006

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Technological Comparison:

Medical Device	Predicate SDOIS	Subject Envisu™ SDOIS
Indications for Use	The Spectral Domain Imaging System (SDOIS) is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). It is primarily intended for the imaging of retinal tissue, but the cornea, sclera and conjunctiva can also be imaged by changing the focal position. Indications for use include the evaluation of ophthalmic tissue in routine clinical examinations and as an aid in the diagnosis of conditions that affect the optical scattering properties of ocular tissue.	Bioptigen Envisu™ Spectral Domain Ophthalmic Imaging system is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT). The Envisu™ SDOIS is indicated for use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in upright or supine imaging, handheld or mounted, and is suited for imaging patients under anesthesia.

Categories	Specifications	
Method of Operation	SD-OCT	Same as predicate
Light Source	SLED High Resolution (HR)	SLED HR: Same as predicate VHR: Very High Resolution
Light Source Classification	Class 1 LED	HR: Same as predicate VHR: Class 1 LED
Optical Power	≤ 750 µW at cornea	Same as predicate
Resolution, Lateral	Retina: 20 µm in tissue Anterior: ~25 µm in tissue	Retina: same as predicate Anterior Segment: 9, 12 and 25 µm
Resolution, Axial	≤ 6 µm in tissue	HR: Same as predicate VHR: <4 µm in tissue
Depth Range (in tissue/air)	1.7 / 2.2 mm	Model C2200: 1.7 /2.3 Model C2300: 2.5 / 3.4 mm
Scanner Type	Galvanometric mirror pair	Same as predicate

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Scan Patterns Available	Line, rectangular volume, circle, concentric rings, radial lines	Same as predicate
Scan Pixels	Axial (depth): 512 or 1024 Lateral : User Selectable Maximum 5,000 A-scans / B-scan Maximum 150,000 total A-scans	Same as predicate
Scan Rate	20,000 A-scans/s	32,000 A-scans/s
Detection	Transmission Grating Spectrometer / Line-Scan Camera	Same as predicate
Scanner Ergonomics	Mounted (tabletop)	Same as predicate or handheld
Patient Interface	Chin Rest Assembly	Same as predicate or None (Chin Rest Assembly now optional)
Footprint	Stationary: 15" x 18" Engine, 12" x 15" scanner	Mobile: 24" x 22" x 37.5"
Scanner Dimensions	12" (h) x 6" (w) x 9"(d)	7" (h) x 3" (w) x 9" (d) h: incl handle / d: incl lens Weight: $\leq$ 3.5 lbs
Software	InVivoVue™ 1.5	InVivoVue™ Clinic 1.4
Operating System	Windows XP	Same as predicate
Processor	Dual 3.4 GHz Xeon	Dual 2.0 GHz Quad Core
Memory	2 GB	4 GB

DEVICE DESCRIPTION

The Envisu™ SDOIS is a non-contact, non-invasive and mobile ophthalmic imaging device that can be used to view ocular tissue physiology and pathology through the interaction of light with the optical scattering properties of structures of the eye.

Like its predicate, the Envisu™ Spectral Domain Ophthalmic Imaging System (SDOIS) is a near-infrared scanning imaging medical device designed to capture depth-resolved images of ocular tissue microstructure. It is available in "high (HR)" and "very-high (VHR)" resolution based on the SLED light source chosen. Each option includes an optical engine, a scanning head, an interchangeable lens set, a computer and the InVivoVue™ Clinic software for imaging of ocular tissue microstructures. The smaller system footprint and mobile security cart easily accommodate any clinical environment.

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Envisu™ System	Maximum Detector Bandwidth (nm)	Maximum Image Depth (mm in tissue)[1]	Pixel Resolution (µm in tissue, 1024 pixels full depth)	Detection Type
C2200	160	1.7	1.6	Transmission Spectrometer, Line-scan Camera
C2300	110	2.5	2.4	

The optical engine includes a low power broadband LED light source with bandwidths of 40 - 100 nm operating in the wavelength range between 760 - 930 nm and a spectrometer that detects backscattered radiation. The scanning head is flexibly designed to be used mounted or handheld for the mutual convenience and comfort of patient and clinician. Handheld use of the light-weight (< 3.5 lbs), compact handheld scanner makes it possible to image pediatric patients, supine patients, or any patient that finds it difficult to sit upright or where it is clinically preferable to image without the constraint of a chin rest. Tabletop, chin-rest mediated imaging is enabled though a mounting accessory.

NON-CLINICAL PERFORMANCE AND SAFETY DATA

IEC-60601-1 electrical, IEC 60601-1-2 electromagnetic compatibility, IEC 60825-1 and ISO 15004-2 Group I optical emission and Class 1 LED safety, image resolution, image comparison and software validation testing have been conducted in accordance with established protocols. All testing has demonstrated compliance with applicable product requirements.

CLINICAL LITERATURE REVIEW

A review of existing peer-reviewed clinical literature publications has been completed. Published clinical data reported that the handheld SDOIS is a safe, noninvasive and effective method for evaluation of the eye for pediatric populations. Clinical testing has not been conducted independently by Bioptigen.

CONCLUSION

The Envisu™ SDOIS has the same fundamental technology, method of operation and technological characteristics as the predicate SDOIS. It introduces new characteristics of mobility and ergonomic utility, including handheld imaging operation, which impact indications for use. Results of performance and safety testing verify that these modifications present no new issues regarding the Envisu™'s safety or effectiveness, and that the Envisu™ SDOIS remains a Class 1 LED , group 1, nonhazardous device eye safe under all operating conditions. In conclusion, the Envisu™ SDOIS is substantially equivalent to the predicate SDOIS device when used as labeled.

[1] Values are approximate, based on an average refractive index of 1.38

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 11 2012

Bioptigen, Inc.
c/o Ms. Dawn Reilly-O'Dell, RAC
Principal Consultant
Full Circle Regulatory Consulting, LLC
104 T.W. Alexander Drive, P.O. Box 13569
Durham, North Carolina 27709

Re: K120057
Trade/Device Name: Envisu Spectral Domain Opthalmic Imaging System (SDOIS) C2200 and C2300
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Codes: HLI, OBO
Dated: May 4, 2012
Received: May 7, 2012

Dear Ms. Reilly-O'Dell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K120057

Device Name: Envisu™ SDOIS (Spectral Domain Ophthalmic Imaging System)

Indications for Use:

Bioptigen Envisu™ Spectral Domain Ophthalmic Imaging System (Envisu™ SDOIS) is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT). The Envisu™ SDOIS is indicated for use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in upright or supine imaging, handheld or mounted, and is suited for imaging patients under anesthesia.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120057